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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,685	10/22/2003	Shigeru Nemoto	KITO2.001DV2	6145
20995 7590 05/01/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER
			3767	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		05/01/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 05/01/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/690,685	Applicant(s) NEMOTO, SHIGERU	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/07 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Botich et al (US Patent No. 5188599). Botich et al discloses a retractable needle system as seen in figures 1-6 comprising a syringe barrel 55 with a tip at a front side of the barrel, with a flange 79 having a projection 83 on a rear surface thereof, also see col. 9 lines 41-50, also wherein the opposite the side of the projection would touch the front wall of the groove; the flange being inherently capable to be held by a flange insertion

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groove so as to fix the syringe barrel; the projection 83 being formed and being inherently capable to be inserted into a flange insertion groove on a cylinder holder and mounted in a use position, the projection 83 has a narrower width toward the tip as can be seen in figure 1; and a tip of the projection 83 being inherently capable of being compressed whereby the flange fully capable of being fitted and fixed into a flange insertion groove due to the size and shape of the flange not severely differing from the normal sizes and shapes of a syringe flange, and due to its ability to perform in the environment, and the projection 83 and the flange 79 together are inherently capable of being inserted into a flange insertion groove and the tip of the projection 83 is capable of being compressed so as to press the flange against a front sidewall surface of the flange insertion groove in a use position due to the size and shape and ability to perform in the environment.

With regards to claim 4, the flange has a two flange cut portions symmetrically positioned in the flange opposite to each other seen in figures 1-3.

With regards to claim 5, the flange has an even number of projections 83 symmetrically disposed to one another on the flange over a portion of the flange where the two flange cut portions are not provided as can be seen in figure 1 where there is a total of 6 projections with an even amount on each side of the flange.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Clements (US Patent No. 5925032). Clements discloses a cylinder holder 10 seen in figures 2-8 comprising a flange insertion groove 17 for holding a syringe barrel; a projection 19 on

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an inner wall surface of the flange insertion groove to be contacted with a rear surface of a flange of the syringe barrel; the projection 19, which is extended from the rear inner wall in the direction of a front wall of the flange insertion groove, being so formed that when the flange is inserted in the flange insertion groove and mounted in a use position, the projection compresses the flange, thereby the flange is fitted and fixed in the flange insertion groove; and wherein the projection has a narrower width toward the tip, see figure 5, whereby the projection is more deformed when compressed. The examiner would like to note that the orientations of the front walls or rear or front surfaces were not fully defined, therefore the rear inner wall is seen to be the wall the projections 19 are attached to as seen in figure 5 and the front wall is the wall opposite the rear inner wall.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clements (US Patent No. 5925032) as applied to claim 9 and further in view of Stanners (5593391). Clements discloses a syringe barrel with a flange to be held by the flange insertion groove. Now even though the syringe barrel in Clements does not disclose a

concave portion attention is directed to Stanners. The Stanners reference discloses a syringe barrel comprising a concave portion formed on the surface of the flange in figures 3 & 15 and it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate a concave portion to the surface of the flange of Clements in order to allow a more secure grip of the projections to the syringe barrel to prevent movement of the syringe barrel.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599). Botich et al discloses an injection system comprising a syringe barrel comprising a flange having a projection being inherently capable of being inserted into a flange insertion groove. Even though the Botich system does not explicitly state the projection to have a pyramid-like shape or a conical shape it would be obvious to one of ordinary skill in the art at the time of the invention to have a pyramid-like shape or conical shape or any other desired shape since applicant does not state the advantages of such shapes and therefore the projections seen in Botich are seen to have an equivalent function, way, and result as the pyramid or conical shape, attention is also directed to MPEP 2144 Section IV B, In Re Dailey for obvious design choice in shape.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599) in view of Bitdinger et al (US Patent No. 5667495). Botich et al discloses an injection system comprising a syringe barrel comprising a flange

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having a projection being inherently capable of being inserted into a flange insertion groove. Even though Botich does not disclose a cylinder holder comprising a flange insertion groove for holding the syringe barrel and a concave portion formed on an inner wall surface of the flange insertion groove to be contacted with the rear surface of the flange of the syringe barrel; whereby, the concave portion is engaged with the projection on the rear surface of the flange when the syringe barrel is mounted in a use position attention is directed to Bitdinger. The Bitdinger reference discloses a cylinder holder 10 in figures 1-20 comprising a flange insertion groove 31 for holding the syringe barrel, and a concave portion (see col 4. line 60 – col 5. line 7) formed on an inner wall surface of the flange insertion groove to be contacted with the rear surface of the flange of the syringe barrel; whereby, the concave portion is inherently capable of engaging the projection on the rear surface of the flange when the syringe barrel is mounted in a use position due to the size, shape, and ability to work in the environment.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al (US Patent No. 5188599) in view of Ritz (US Patent No. 3438549) or Tompkins (US Patent No. 4030498). Even though Botich does not disclose a pre-filled syringe attention is directed to Ritz or Tompkins. The Ritz and Tompkins references both disclose pre-filled syringes and it would be obvious to one of ordinary skill in the art at the time of the invention to have the syringe to be pre-filled for ease of use and to save time also attention is directed to Tompkins col 1. lines 15-17 where it states that "... many syringes are pre-filled ...".

Response to Arguments

Applicant's arguments filed 4/18/07 have been fully considered but they are not persuasive.

Applicant argues that due to the amendments that the front and rear surfaces of the flange have been defined, the examiner disagrees. Since no language has been entered which describe the orientations of the rest of the sides to the surfaces of the flanges, the rejection still stands. Also, the examiner would like to note that claim 1 does not positively claim the cylinder holder and therefore the syringe of Botich is seen to be fully capable of performing all the functional limitations of the claims. It is suggested to the applicant to amend the claims to further clarify the orientations of the surfaces/sides with respect to each other. With respect to claim 8, wherein the orientations here still have not been fully defined and wherein the concave portion is seen to be fully capable of engaging the projection on the rear surface of the flange. Also, wherein the claim does not state on which inner wall the concave portion is formed in claim 8.

Applicant's arguments with respect to claims 9-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pechmann (US Patent No. 3253592) also discloses a syringe barrel that is fully capable of being mounted on a cylinder holder having a projection on a rear surface and wherein the projection has a narrower width toward the tip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

